CLAIMS

At least the following is claimed:

1. A method for diagnosing inflammatory bowel disease (IBD), comprising the steps of:

determining whether a sample obtained from a mammal is positive for anti-flagellin antibodies (AFA); and

diagnosing the individual as having IBD when the sample is positive for AFA, and diagnosing the individual as not having IBD when the sample is negative for AFA.

2. The method of claim 1, wherein the sample is chosen from blood, serum, saliva, stool and tissue.

3. The method of claim 1, wherein AFA positivity is determined using an enzyme-linked immunosorbent assay (ELISA).

4. The method of claim 1, wherein AFA positivity is determined using an assay type chosen from flow cytometry, phage display technology, immunoassays, laser-induced fluorescence, radioimmunoassays, chemiluminescent markers, and fluorochromatic assays.

5. The method of claim 4, wherein the immunoassay is chosen from a competitive immunoassay and a non-competitive immunoassay.

6. The method of claim 5, wherein the immunoassay is chosen from a capillary electrophoresis based immunoassay and a liposome immunoassay.

7. A method, comprising the steps of:

determining whether a sample obtained from a mammal has an anti-flagellin antibodies (AFA) level above an AFA cut-off value (X); and

diagnosing the individual as having inflammatory bowel disease (IBD) when the AFA level is above X, and diagnosing said individual as not having IBD when the AFA level is below X, wherein X is independently selected to achieve an optimized clinical parameter chosen from at least one of the following: sensitivity, specificity, negative predictive value, positive predictive value, and overall agreement.

8. The method of claim 7, wherein the sample is chosen from blood, serum, saliva, stool and tissue.

9. The method of claim 7, wherein AFA level is determined using an enzyme-linked immunosorbent assay (ELISA).

10. The method of claim 7, wherein AFA positivity is determined using an assay type chosen from flow cytometry, phage display technology, immunoassays, laser-induced fluorescence, radioimmunoassays, chemiluminescent markers, and fluorochromatic assays.

11. A method, comprising the steps of:

contacting an appropriate dilution of a sample obtained from a mammal with an antigen specific for anti-flagellin antibodies (AFA) under conditions suitable to form a complex of AFA and the antigen specific for AFA;

determining the amount of the complex; and

diagnosing the mammal as having IBD when the amount of the complex formed is greater than an AFA cut-off value (X), and diagnosing the mammal as not having IBD when the amount of the complex formed is less than X, wherein X is independently selected to achieve an optimized clinical parameter chosen from at least one of the following: sensitivity, specificity, negative predictive value, positive predictive value and overall agreement,

provided that said method does not include histological analysis of flagellin.

12. The method of claim 11, wherein the sample is at least one of a serum sample, a saliva sample, a blood sample, a stool sample, and a tissue sample.

13. The method of claim 11, wherein the antigen specific for AFA is fixed flagellin.

14. The method of claim 11, wherein the amount of the complex is determined using at least one of the following assays: an enzyme-linked immunosorbent assay (ELISA), flow cytometry, phage display technology, an immunoassays, laser-induced fluorescence, radioimmunoassays, chemiluminescent markers, and fluorochromatic assays.

15. A test kit for determining the concentration of anti-flagellin antibodies (AFA) present in a sample, comprising:

a substrate comprising a coating of purified flagellin;

a standard with a known concentration of AFA;

a detection antiserum labeled with a chromogenic indicator capable of color development when exposed to a developing solution;

a developing solution; and

an assay wash buffer.

16. The test kit of claim 15, further comprising a color chart indicating known AFA concentrations corresponding to a plurality of discernible colors.

17. The test kit of claim 15, further comprising directions for use.

18. A method, comprising the steps of:

contacting a sample obtained from a mammal with a substrate coated at least in part with purified flagellin;

contacting the substrate with a detection antiserum labeled with a chromogenic indicator capable of color development when exposed to a developing solution;

contacting the developing solution with the substrate; and

detecting the presence of a plurality of AFA.

19. The method of claim 18, further comprising the step of determining whether the mammal has IBD based on the presence or absence of AFA.

20. The method of claim 18, further comprising the step of determining whether the mammal has IBD based on an amount of AFA present.

21. A method for diagnosing inflammatory bowel disease (IBD), comprising the steps of:

determining whether a sample obtained from a mammal is positive for anti-flagellin antibodies (AFA); and

diagnosing the individual as likely having IBD when the sample is positive for AFA, and diagnosing the individual as probably not having IBD when the sample is negative for AFA.

22. The method of claim 21, wherein determining whether a sample obtained from a mammal is positive for AFA comprises measuring both IgG AFA and IgA AFA.